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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,394	05/03/2000	THOMAS CARLSSON	45687-00008	5034

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EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/462,394

Applicant(s)

CARLSSON, THOMAS

Examiner

Yelena G. Gakh, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Amendment filed on 01/09/04 is acknowledged. Claims 12-18 are cancelled without prejudice. Claims 1-11 are pending in the application.

#### *Response to Amendment*

2. Objection to the specification is withdrawn in view of the amendment. Rejection of the pending claims over Luong et al. (US 5,411,866) is withdrawn in view of the Applicant's remarks (see below).

#### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. **Claims 1-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Edelmann et al. (US 4,153,513, IDS) in view of Wong (US 5,165,406).

Edelmann teaches a method "for the continuous determination of the concentration of an enzyme substrate" (Title) in a blood sample, comprising "an intermittent introduction in which the volumes of sample move block-like in the current of buffer solution" (col. 3, lines 40-50) with pure buffer solution flowing through the detector between the measurements.

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Anticoagulant is mixed with the blood sample in 1:1 ratio (5 ml/hr of heparin solution and 5 ml/hr of blood, col. 6, lines 53-56), the measurements are performed every 30 sec (col. 4, lines 56-60).

Edelmann does not specifically disclose regenerating the biosensor by increasing the flow rate of the buffer after detecting the analyte.

Wong discloses an electrochemical biosensor apparatus for detecting blood analytes and a method of its regeneration comprising washing step between the measurements, which involves turbulent agitating flow of infusion or calibration liquid "that helps dislodge any blood cells collected around the electrodes, as well as other parts of the assembly. This reduces the collection of blood cells, increases the measurement accuracy, and reduces the purge volume necessary for accurate measurement, thereby reducing the time interval between successive measurements" (col. 3, lines 37-46).

Although Wong does not specifically indicate increasing the flow rate of the washing buffer between measurements (i.e. after the signal is detected and until the zero background is achieved), turbulent flow has the same effect as increased rate of a laminar flow; therefore it would have been obvious for anyone of ordinary skill in the art to modify Edelmann's method by simply increasing the flow rate of the washing buffer between measurements instead of using specially designed helical groove for creating turbulent flow disclosed by Wong, because such increase of the flow rate has the same effect of more efficient cleaning the sensor, as Wong's turbulent flow. It would have been obvious for anyone of ordinary skill in the art to optimize this rate to make it higher than the rate of the analyte flow (10 ml/hr).

### ***Response to Arguments***

6. Applicant's arguments filed 01/09/04 have been fully considered but they are not completely persuasive. The examiner agrees with the Applicant's arguments regarding Luong et al., since Luong in fact discusses the flow rate of the sample flow, rather than the flow rate of the buffer, although he indicates a non-zero baseline due to the slow dissociation of glutamate for the resin during the washing step. However, the examiner does not agree with the Applicant's arguments regarding combination of Edelmann and Wong. Wong specifically discloses

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advantages of using turbulent flow of the calibrating (washing) liquid for regenerating his biosensor. Edelmann teaches all steps of the method disclosed in the instant application except for increasing the flow rate of the washing buffer. It is notoriously well known to any routineer in the art that the laminar and turbulent flows are both described with the Reynolds number (see "The Onset of Turbulent Flow"), and that they are interconverting through their flow rate. The laminar flow with the flow rate, which exceeds a specific value turns into the turbulent flow. It would have been absolutely obvious for anyone of ordinary skill in the art to increase the flow rate of the washing buffer in Edelmann's method for the reasons expressly indicated by Wong: "that helps dislodge any blood cells collected around the electrodes, as well as other parts of the assembly. This reduces the collection of blood cells, increases the measurement accuracy, and reduces the purge volume necessary for accurate measurement, thereby reducing the time interval between successive measurements" (col. 3, lines 37-46) without using Wong's complex design, but rather just by increasing the laminar flow rate of the washing buffer (which can actually become the turbulent flow at a specific speed).

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### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Yelena Gakh  
3/20/04

